UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, v. AMERICAN REGENT, INC., Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their complaint against American Regent, Inc. ("American Regent"), hereby allege as follows:

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, American Regent, Inc. is a corporation organized and existing under the laws of New York, having its principal place of business at 5 Ramsey Road, Shirley, New York 11967. Upon information and belief, American Regent is a pharmaceutical company engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent") 9,744,209 ("the '209 Patent"), and 9,750,785 ("the '785 Patent") (collectively, "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement).

7. This Court has personal jurisdiction over American Regent because, *inter alia*, American Regent has purposely availed itself of the benefits and protections of the laws of Delaware. In addition, on information and belief, American Regent has had continuous and systematic contacts with this judicial district, including conducting business in Delaware and marketing, selling, and distributing pharmaceutical products throughout the United States and in this judicial district.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) because, *inter alia*, American Regent has engaged in a course of conduct to seek approval for, manufacture, distribute, market, and sell the infringing products throughout the United States, including in this judicial district, and has agreed not to challenge venue in this district with respect to this lawsuit.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

10. Alternatively, a company may seek approval to market a new drug product by filing an NDA under 21 U.S.C. § 355(b)(2) (a "§ 505(b)(2) application") which refers to and relies in part on the safety and efficacy findings of a previously approved drug (referred to as a "reference listed drug"), typically one that was approved under an original NDA filed pursuant to 21 U.S.C. § 355(b)(1).

11. By allowing an applicant to piggy-back on the innovator company's investment in clinical or other studies relating to the previously approved, reference listed drug, the abbreviated § 505(b)(2) application process can provide a shorter and less costly drug development pathway for the applicant than exists for an applicant filing an original NDA.

12. In conjunction with this § 505(b)(2) application process, Congress has put in place a process for resolving patent disputes relating to § 505(b)(2) application products, pursuant to which a § 505(b)(2) applicant must provide certifications addressing each of the patents listed in the Orange Book for the reference listed drug. *See* 21 U.S.C. § 355(b)(2)(A). *See also* 21 C.F.R. §§ 314.50(i), 314.54. The applicant may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the § 505(b)(2) application product. *See* 21 U.S.C. §355(b)(2)(A)(iv); 21 C.F.R. § 314.50(i)(1)(i)(A)(4). This is known as a "Paragraph IV Certification."

13. A § 505(b)(2) applicant that includes a Paragraph IV Certification with its application must also provide notice to both the owners of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases supporting the § 505(b)(2) applicant's belief that the challenged patent is invalid or not infringed by the proposed § 505(b)(2) application product. *See* 21 U.S.C. § 355(b)(3); 21 C.F.R. § 314.52.

14. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from a § 505(b)(2) applicant, final approval of the § 505(b)(2) application is subject to a 30-month stay. *See* 21 U.S.C. § 355(c)(3)(C). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to an infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the § 505(b)(2) application product enters the market. *See* 21 U.S.C. § 355(c)(3)(C).

FACTUAL BACKGROUND

The Patents-In-Suit

15. On June 28, 2016, the PTO duly and legally issued the '478 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '478 Patent is attached as Exhibit A. Par Pharmaceutical owns the '478 Patent.

16. On June 27, 2017, the PTO duly and legally issued the '526 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '526 Patent is attached as Exhibit B. Par Pharmaceutical owns the '526 Patent

17. On August 29, 2017, the PTO duly and legally issued the '209 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '209 Patent is attached as Exhibit C. Par Pharmaceutical owns the '209 Patent.

18. On September 5, 2017, the PTO duly and legally issued the '785 Patent, entitled "Vasopressin Formulations For Use In Treatment Of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '785 Patent is attached as Exhibit D. Par Pharmaceutical owns the '785 Patent.

19. EPIC is the exclusive licensee of the Patents-In-Suit.

VASOSTRICT®

20. Vasopressin, the active ingredient in VASOSTRICT® (described below), is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells.

VASOSTRICT® is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

21. On September 25, 2012, JHP Pharmaceuticals ("JHP") submitted NDA No. 204485, under §505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock. On April 17, 2014, the FDA approved NDA 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

22. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP Pharmaceuticals, LLC. On February 26, 2014, JHP Pharmaceuticals, LLC changed its name to Par Sterile Products, LLC.

23. Par Sterile Products submitted supplemental NDAs including supplemental NDA Nos. 204485/S-003 and 204485/S-004 for the current formulations of VASOSTRICT®—20 units/mL in 1 mL vials and 200 units/10 mL in 10 mL multi-dose vials. On March 18, 2016, the FDA approved NDA No. 204485/S-003 for the 20 units/mL in 1 mL vial formulation of VASOSTRICT®. On December 17, 2016, the FDA approved NDA No. 204485/S-004 for the 200 units/10 mL in 10mL vial formulation of VASOSTRICT®.

24. Par Sterile Products is the holder of NDA 204485, including all supplements thereto, for VASOSTRICT®.

25. Par timely submitted information regarding the Patents-in-Suit for listing in the "Orange Book" with respect to VASOSTRICT®, pursuant to 21 U.S.C. § 355(b)(1) and (c)(2). The FDA thereafter listed the Patents-in-Suit in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

26. VASOSTRICT® is FDA-approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers. VASOSTRICT® has enjoyed tremendous commercial success, with 2017 annual sales of $400 million.

American Regent's Infringing Vasopressin Injection Product

27. Upon information and belief, American Regent has submitted NDA No. 212593 (the "American Regent NDA") to the FDA pursuant to 35 U.S.C. § 355(b)(2), seeking approval to engage in the commercial manufacture, use, and sale of a proposed Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product, referencing Par's VASOSTRICT® products as the reference listed drug (the "Proposed NDA Product").

28. On or about June 27, 2019, American Regent sent Par Sterile Products and Par Pharmaceutical a notice stating that American Regent had submitted the American Regent NDA seeking approval to manufacture, use, or sell the Proposed NDA Product prior to expiration of the Patents-in-Suit (the "Paragraph IV Notice").

29. The Paragraph IV Notice advised that American Regent's NDA includes Paragraph IV Certifications stating that it is American Regent's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed NDA Product.

30. Upon information and belief, if American Regent were to obtain FDA approval to market and sell its Proposed NDA Product, it would market and sell them throughout the United States, including in this District.

COUNT I:
INFRINGEMENT OF THE '526 PATENT

31. Par incorporates each of the preceding paragraphs as if fully set forth herein.

32. American Regent's submission of the American Regent NDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed NDA Product prior to the expiration of the '526 Patent, constitutes infringement of the '526 Patent under 35 U.S.C. § 271(e)(2)(A).

33. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product before expiration of the '526 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '526 Patent under 35 U.S.C. §§ 271(a)-(c).

34. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product would lead to such infringement of at least claim 1 of the '526 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising: i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof; ii) acetic acid; and iii) water,
> wherein the pharmaceutical composition has a pH of 3.8;
> b) storing the pharmaceutical composition at 2-8º C. for at least 4 weeks; and
> c) intravenously administering the pharmaceutical composition to the human,
> wherein the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute,
> wherein the human is hypotensive,
> wherein the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8º C. for about four weeks.

35. If the Proposed NDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, American Regent would actively and intentionally induce such infringement.

36. Any launch by American Regent of its Proposed NDA Product before expiration of the '526 Patent would cause Par to suffer immediate and irreparable harm.

37. Upon information and belief, American Regent was aware of the existence of the '526 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product will lead to infringement of the '526 Patent.

38. American Regent's infringement of the '526 Patent is willful.

COUNT II:
INFRINGEMENT OF THE '209 PATENT

39. Par incorporates each of the preceding paragraphs as if fully set forth herein.

40. American Regent's submission of the American Regent NDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed NDA Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

41. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product before expiration of the '209 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

42. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:

the unit dosage form has a pH of 3.7-3.9;

the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and

the human is hypotensive.

43. If the Proposed NDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, American Regent would actively and intentionally induce such infringement.

44. Any launch by American Regent of its Proposed NDA Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

45. Upon information and belief, American Regent was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product will lead to infringement of the '209 Patent.

46. American Regent's infringement of the '209 Patent is willful.

COUNT III:
INFRINGEMENT OF THE '478 PATENT

47. Par incorporates each of the preceding paragraphs as if fully set forth herein.

48. American Regent's submission of the American Regent NDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed NDA Product prior to the expiration of the '478 Patent, constitutes infringement of the '478 Patent under 35 U.S.C. § 271(e)(2)(A).

49. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product before expiration of the '478 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '478 Patent under 35 U.S.C. §§ 271(a)-(c).

50. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product would lead to such infringement of at least claim 1 of the '478 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form consists essentially of:
> s) from about .01 mg/mL to about .07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> b) 10 mM acetate buffer; and
> c) water,
> wherein:
> the unit dosage form has a pH of 3.8;
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
> the human is hypotensive.

51. If the Proposed NDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, American Regent would actively and intentionally induce such infringement.

52. Any launch by American Regent of its Proposed NDA Product before expiration of the '478 Patent would cause Par to suffer immediate and irreparable harm.

53. Upon information and belief, American Regent was aware of the existence of the '478 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product infringes the '478 Patent.

54. American Regent's infringement of the '478 Patent is willful.

COUNT IV:
INFRINGEMENT OF THE '785 PATENT

55. Par incorporates each of the preceding paragraphs as if fully set forth herein.

56. American Regent's submission of the American Regent NDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed NDA Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

57. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product before expiration of the '785 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

58. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

> Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

59. The Proposed NDA Product satisfies each of the elements of the pharmaceutical composition recited in claim 1, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product by American Regent would constitute infringement of claim 1 of the '785 Patent.

60. Any launch by American Regent of its Proposed NDA Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

61. Upon information and belief, American Regent was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed NDA Product infringes the '785 Patent.

62. American Regent's infringement of the '785 Patent is willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. A judgment that American Regent has infringed the '526 Patent, and a declaration that American Regent's commercial manufacture, distribution, use, and sale of its Proposed NDA Product would infringe the '526 Patent;

B. A judgment that American Regent has infringed the '209 Patent, and a declaration that American Regent's commercial manufacture, distribution, use, and sale of its Proposed NDA Product would induce infringement of the '209 Patent;

C. A judgment that American Regent has infringed the '478 Patent, and a declaration that American Regent's commercial manufacture, distribution, use, and sale of its Proposed NDA Product would infringe the '478 Patent;

D. A judgment that American Regent has infringed the '785 Patent, and a declaration that American Regent's commercial manufacture, distribution, use, and sale of its Proposed NDA Product would induce infringement of the '785 Patent;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of American Regent's NDA No. 212593 and/or of the Proposed NDA Product shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

F. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining American Regent, its officers, agents, servants and employees,

and those person in active concert or participation with any of them, from infringement of the Patents-in-Suit for the full terms thereof, including any extensions;

G. An order that damages or other monetary relief be awarded to Plaintiffs if American Regent engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of American Regent's Proposed NDA Product, or induces such conduct by others, prior to the expiration of the Patents-in-Suit, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment and post judgment interest;

H. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Plaintiffs in this action; and

I. Such other and further relief as the Court may deem just and proper.

Dated: August 9, 2019

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Respectfully submitted,

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